

AMENDMENTS TO THE SPECIFICATION

On page 1 of the specification:

Please insert after the Title and prior to the first line the sentence. -- This application is a nonprovisional application of provisional application serial No. 60/527,084, filed December 4, 2003. --

On page 21, lines 12-29:

Further description of suitable dissolution enhancers and selection of appropriate excipients for azithromycin multiparticulates are disclosed in U.S. Patent Application Serial No. 11/003,853 ("Controlled Release Multiparticulates Formed with Dissolution Enhancers," Attorney Docket No. PC25016), filed concurrently herewith.

In a more preferred embodiment, the multiparticulates of the present invention comprise (a) azithromycin; (b) a glyceride carrier having at least one alkylate substituent of 16 or more carbon atoms; and (c) a poloxamer dissolution enhancer. The choice of these particular carrier excipients allows for precise control of the release rate of the azithromycin over a wide range of release rates. Small changes in the relative amounts of the glyceride carrier and the poloxamer result in large changes in the release rate of the drug. This allows the release rate of the drug from the multiparticulate to be precisely controlled by selecting the proper ratio of drug, glyceride carrier and poloxamer. These materials have the further advantage of releasing nearly all of the drug from the multiparticulate. Such multiparticulates are disclosed more fully in U.S. Patent Application Serial No. 11/004,168 ("Multiparticulate Crystalline Drug Compositions Having Controlled Release Profiles," Attorney Docket No. PC25020), filed concurrently herewith.

On page 34, lines 1-4:

Suitable liquid-based processes are disclosed more fully in U.S. Patent Application Serial No. 11/004,453, Attorney Docket No. PC25018, titled "Improved Azithromycin Multiparticulate Dosage Forms by Liquid-Based Processes", filed concurrently herewith.

On page 36, lines 30-33:

Patent Application  
Attorney Docket No. PC25240A  
EXPRESS MAIL EV581868693US

Processes to maintain the crystalline form of azithromycin while forming multiparticulates are disclosed more fully in U.S. Patent Application Serial No. 11/003,659 (“Method for Making Pharmaceutical Multiparticulates,” Attorney Docket No. PC25021), filed concurrently herewith.

On page 37, lines 1-13:

The multiparticulates of the present invention may be post-treated to improve the drug crystallinity and/or the stability of the multiparticulate. In one embodiment, the multiparticulates comprise azithromycin and a carrier, wherein the carrier, when in the multiparticulate, and containing the azithromycin and optional excipients has a melting point of  $T_m$  in °C; the multiparticulates are treated after formation by at least one of (i) heating the multiparticulates to a temperature of at least 35°C but less than ( $T_m$  °C - 10°C), and (ii) exposing the multiparticulates to a mobility-enhancing agent. Such a post-treatment step results in an increase in drug crystallinity in the multiparticulates, and typically an improvement in at least one of the chemical stability, physical stability, and dissolution stability of the multiparticulates. Post-treatment processes are disclosed more fully in U.S. Patent Application Serial No. 11/003,664, (“Multiparticulate Compositions with Improved Stability,” Attorney Docket No. PC11900) filed concurrently herewith.

On page 38, lines 13-19:

Processes for reducing ester formation are described in more detail in commonly assigned U.S. Patent Application Serial Nos. 11/003,856 (“Improved Azithromycin Multiparticulate Dosage Forms by Melt-Congeal Processes,” Attorney Docket No. PC25015), 11/003,853 (“Controlled Release Multiparticulates Formed with Dissolution Enhancers,” Attorney Docket No. PC25016), and 11/004,453 (“Improved Azithromycin Multiparticulate Dosage Forms by Liquid-Based Processes, Attorney Docket No. PC25018), filed concurrently herewith.